0.05) on the SF 12. Properly monitored patients spent significantly more on total health care services (+$5243), outpatient visits (+$1023), and medications (+$1204), respectively (all *P*-values<0.05). **CONCLUSIONS:** In the US, nearly 40% patients with diabetes do not receive the proper diabetes monitoring controlling for racial and socioeconomic disparities. Anti-diabetics/insulin use, mental/cognitive status, physical health status, and health care expenditure may also interact with performing monitoring. Barriers and cost-benefit for long-term monitoring should be studied.

PDB90

IMPROVING PATIENT CARE: RESULTS FROM THE TEXAS NEWBORN SCREENING PERFORMANCE MEASURES PROJECT

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BACKGROUND: Advances in screening technology have led to rapid expansion of newborn screening as a public health initiative in the United States. Due to variation across states in program implementation, there is a lack of standardization and accountability, which can affect quality of care. Texas currently screens for 28 disorders. **OBJECTIVES:** The Texas Newborn Screening Performance Measures Project was initiated with the objective of developing evidence-based performance measures to improve quality, accountability and uniformity in the care. **METHODS:** A three step approach was used for identification and development of key measures for seven most critical disorders: systematic reviews; impact assessment; and feasibility assessment. Impact assessments (likert scale) were based on National Quality Measures Clearinghouse™ (NQMC) criteria: scientific soundness, relevance, health importance, impact on quality of care, and ability to address disparities in care. A likert scale was also used for feasibility assessment on key aspects: data availability, ease of collection, infrastructure and human resource needs, overall cost, and time constraints. **RESULTS:** A total of 50 performance measures were supported by scientific evidence. Impact and feasibility assessments led to the approval of 33/50 measures. "Time to initiate treatment" received the highest scores on potential impact on patient outcomes (mean impact score 86.67/100, SD 1.5). Other measures with potentially high impact (score >80/100) were: compliance with oral prophylactic medication and age at first Prevnar® vaccination in sickle cell disease; screening of at-risk family members in fatty acid disorders; frequency of growth assessments in congenital adrenal hyperplasia and phenylalanine levels in phenylketonuria. "Time to treatment" for individual disorders was also ranked very high on feasibility (mean feasibility score 88.67/100, SD 3.88). **CONCLUSIONS:** This is one of the first efforts to identify and develop evidence-based performance measures in newborn screening and can pave the way for system wide changes and development of national guidelines.

PDB91

TREATMENT PATTERNS AND ACHIEVEMENT OF THERAPEUTIC GOALS IN A COHORT OF TYPE 2 DIABETES MELLITUS PATIENTS TREATED IN THE BRAZILIAN PRIVATE HEALTH CARE SYSTEM (PHCS): INITIAL REPORTS OF DIAPS 79 STUDY

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OBJECTIVES: Investigate the type 2 diabetes mellitus (T2DM) treatment practice and achievement of therapeutic goals in a cohort of T2DM patients treated in the Brazilian PHCS. **METHODS:** This is a cross-sectional analysis of 383 T2DM outpatients treated in 5 cities covered by the PHCS. Data was collected using information from the previous year by interviewing patients using a validated questionnaire complemented by medical chart review. Therapeutic goals suggested by the Brazilian Diabetes Society were used as standard treatment. **RESULTS:** Mean age was 60.5 ± 9.6 years, mean BMI 29.1 ± 5.3 Kg/m2 and mean duration of diabetes of 12.2 ± 8.75 years. The frequency of associated arterial hypertension was 66.8% (n = 256); obesity 39% n = 144); dyslipidemia 69.6% (n = 267) and heart failure 5.5% (n = 21). Microvascular complications were present in 32.4% (n = 124); 8.1% (n = 31) had macrovascular complications; 18% (n = 69) had at least one micro and one macrovascular complication and 41.5% (n = 159) had no complications. Current treatment practice was: 3.6% (n = 14) diet only; 30% (n = 115) monotherapy with oral anti-diabetic (OAD); 37.8% (n = 145) combined therapy with more than one OAD agents; 23.2% (n = 89) combined therapy with insulin and 5.2% (n = 20) just insulin. The most prescribed drug was metformin (41.4%), followed by insulin (19.1%), sulphonylureas (18.6%), DPP4 inhibitors (8.7%), TZDs (5.5%), and others (6.7%). Medications for dyslipidemia was used by 47.5% (n = 178); cardiovascular drugs in 77.4% (n = 287) and anti-obesity drugs in 4% (n = 15). Treatment targets were achieved in: 76.8% for systolic and diastolic blood pressure (<130 × 85 mmHg), 19.5% for BMI < 25 kg/m2, 28% for HDL cholesterol >55 women, 37.3% for HDL cholesterol >45 men and 28.2% reached the goal for HbA1c (within normal range). Only 6.8% of the group (n = 26) reached all the treatment targets. **CONCLUSIONS:** The national goals for glycemic control, blood pressure and lipid levels are rarely achieved in real-world clinical practice, even with the high use of medications.

DIABETES/ENDOCRINE DISORDERS – Conceptual Papers & Research on Methods

PDB92

CLINICAL AND ECONOMIC CONSEQUENCES OF THE PHARMACOLOGICAL HYPOGLYCEMIC TREATMENT OF TYPE 2 DIABETES IN CROATIA

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OBJECTIVES: Diabetes mellitus type 2 (T2DM) is a chronically progressive disease and the treatment must be selected according to the pathophysiological phase of the disease at the time the treatment is begun. The Croatian public diabetology sector takes care of approximately 150,000 adults treated with oral hypoglycemic agents (OHA) alone or in combination with insulin. Our objective was assessment of the clinical and economic consequences of OHA treatment in T2DM from a Croatian health care system perspective. **METHODS:** The target population defined for the study was diabetic patients treated with OHA alone. Medication consumption was quantified by using Pharmis and CroDiab data. a clinical expert panel provided resource-use information not available in published literature or health care databases. **RESULTS:** Current consumption data is showing that 62.8% patients are using OHA as monotherapy. Within this group, majority is using either biguanides or sulphonylureas. Patients treated with sulphonylureas are represented with almost the same percentage as those treated with biguanides (25% vs. 29%). Combination of two OHA is used in 34.2% while 3% of patients are treated by triple therapy. The most often choice in dual therapy is combination of biguanides and sulphonylureas while biguanides, sulphonylureas and thiazolidinediones in combination as the most favourable treatment option in triple therapy. Biguanides are used as a one of OHA in 61% of patients. **CONCLUSIONS:** Considering current clinical guidelines, lifetime benefits of biguanides and facts that they are low-cost agent, relatively small proportion of T2DM patients are treated with this agent in Croatia. Findings of this investigation revealed real life pattern of T2DM treatment, which enables directing in better treating and more cost-effective management in Croatia.

PDB93

THE RELIABILITY OF PROPORTION OF DAYS COVERED CALCULATIONS USING DEFINED DAILY DOSE ESTIMATES

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OBJECTIVES: Using a large, US administrative pharmacy claims database, calculate proportion of days covered (PDC) using actual days supply, and compare estimated PDC (ePDC) using days supply derived from drug-specific Defined Daily Dose (DDD) criteria. **METHODS:** Continuously eligible patients filling non-insulin anti-diabetic medication were targeted from a large sample of pharmacy claims during 2008 and 2009. Medications were grouped into ATC diabetes drug classes. Proportion of days covered (PDC) was calculated as the number of days a patient had medication in their possession divided by the number of days in the period. PDC was first calculated using actual days supply, then ePDC was calculated using an estimated days supply from DDD, strength, and pill quantity. The percent of patients adherent to therapy was defined by a PDC > 0.80. The reliability of each method was assessed by Pearson correlation coefficients and agreement above chance was assessed using Kappa statistics. **RESULTS:** Adherence was calculated for 163,750 patients taking non-insulin anti-diabetics. Overall, the PDC was 0.69 and ePDC 0.57. The two measures were also highly and significantly correlated ($r = 0.73$; $P < 0.0001$). The percent adherent was 48.8% (PDC) and 34.4% (ePDC), (Kappa = 0.50; $P < 0.0001$). At the medication class level, differences in PDC and ePDC ranged from 0.01 to 0.35, with correlation coefficients ranging from 0.40 to 0.93. Differences in the percent adherent metric ranged from –2.3 to 23.2, and kappa values from 0.22 to 0.89. **CONCLUSIONS:** Applying DDD estimates for the purposes of diabetes adherence estimation when lacking days supply values may provide reasonable estimates of adherence based on results presented here. At the medication class level there is greater variability in the reliability measures. Including claims from the U.S. only is a limitation of this analysis, as local treatment patterns may vary, and DDD values were not available for all U.S. medications.

PDB94

MARKOV AND MONTE-CARLO MODELS IN THE PROGRESSION OF DIABETES MELLITUS: A LITTERATURE REVIEW TO IDENTIIFY THE FACTORS INFLUENCING THE CHOICE OF THE TYPE OF MODEL

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OBJECTIVES: Markov and Monte-Carlo (MC) models are often used to simulate Diabetes Mellitus (DM) and its complications over time, but reasons to choose the model type are poorly documented. a systematic literature review was performed to identify factors influencing the choice of the model type. **METHODS:** Models simulating the progression of DM and its complications were selected from Medline and Embase databases. Literature reviews, methodological articles and non original models were excluded. Each full-paper selected went through a 31-item checklist via a double-reading process. a qualitative analysis was performed to evaluate the accuracy of the model with the study question. **RESULTS:** Sixty-one models were selected, including

42 Markov and 19 MC. Median time since publication was 6 years. Most models concerned Type 2 DM (57%) and prevention or disease-management programs (54%). In average, models had 11 states and 2.8 complications. MC were significantly more used than Markov when both type 1 and 2 DM and a prevention or disease management program were concerned. Models had, significantly, a higher number of states and complications. The choice of the model type was shown to be influenced by the number of DM and of complications considered. The justification to perform a Monte-Carlo was more often documented than those to perform a Markov (74% vs. 38%). The model was considered accurate with the study question in respectively 86% of Monte-Carlo and 64% of Markov. **CONCLUSIONS:** This study allowed to statistically identify factors influencing the type of model used to simulate DM. It is an interesting tool for modelers in their decision process to build a model. Information such as data and time availability or financial context could not be collected.

PDB95

SIMPLIFICATION OF PATIENT LEVEL SIMULATIONS TO COHORT MODEL FOR SCENARIO ANALYSIS

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OBJECTIVES: In the last 15 years, models built to appraise health technologies have grown in complexity to accurately reflect the natural history of disease and calculate costs and benefits accordingly. The advantage of using patient level simulation models (PSM) over cohort models (CM) is that CM may become unwieldy with thousands of branches. This usually happens if the patient characteristics influence the risks of complications and these vary over time, or if there are many comorbidities to take into account and the risk of each complication is time dependent. In this case, a typical Markov cohort may be unsuitable. However a PSM can take a long time to run in order to produce results. Aim of this research is to present a case study where a PSM is simplified with a Markov structure and to compare the results of the two models. **METHODS:** We describe how a PSM for diabetes may be adapted to a CM, stating all the limitations. **RESULTS:** Provided that the PSM gives similar answers to the CM, the CM may be used as a surrogate for conducting complex sensitivity analysis (e.g., 3-way analysis or tornado diagrams). The advantage is that this model would produce results "instantaneously." **CONCLUSIONS:** The adaptation of a PSM model to a cohort model may be a desirable feature if the model is required by a non technical audience. This is the case for "due diligence" models that are increasingly required by investors to assess the value of assets that a pharmaceutical company considers to buy or sell. Further research is needed to have a powerful test to assess whether the difference in results between a simplified CM model and the PSM are statistically significant.

MUSCULAR-SKELETAL DISORDERS – Clinical Outcomes Studies

PMS1

HIGHER COMORBIDITIES IN PATIENTS WITH GOUT VS. WITHOUT GOUT IN THE US GENERAL POPULATION: THE NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY (NHANES) 2007–2008

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OBJECTIVES: While the comorbidity burden of gout in the US has been considered substantial and may have been rising over the past decade, no contemporary national data are available. We estimated the prevalence of major comorbidities in patients with gout compared with those without gout based on a recent, nationally representative sample of US men and women (National Health and Nutrition Examination Survey [NHANES] 2007–2008). **METHODS:** Using data from 5707 participants in NHANES 2007–2008 (2797 men and 2910 women) aged 20 years and older, we determined the prevalence of major comorbidities among individuals with gout, including hypertension, renal impairment, nephrolithiasis, diabetes, myocardial infarction, heart failure, stroke, and obesity. We also compared the prevalence with those without gout using age- and sex-adjusted logistic regressions. Case definitions of comorbidities were based on an affirmative answer to a question asking if a physician or a health professional had diagnosed the corresponding condition. **RESULTS:** Among US adults with gout, 74% had hypertension, 53% obesity, 26% diabetes, 24% nephrolithiasis, 14% myocardial infarction, 11% heart failure, 10% stroke, and 9% renal impairment (Table). Prevalence of these comorbidities among individuals with gout was substantially higher than among individuals without gout. Age- and sex-adjusted odds ratios (95% confidence interval [CI]) were 4.19 (2.75–6.39) for hypertension, 2.35 (1–55–3.57) for obesity, 2.36 (1.49–3.73) for diabetes, 2.10 (1.39–3.18) for nephrolithiasis, 2.37 (1.54–3.65) for myocardial infarction, 2.68 (1.88–3.83) for heart failure, 2.02 (0.98 to 4.19) for stroke, and 3.50 (2.05–5.98) for renal impairment. **CONCLUSIONS:** These findings from the latest nationally representative sample of US adults in NHANES 2007–2008 confirm that the prevalence of comorbidities among individuals with gout is substantial and considerably higher than among individuals without gout.

PMS2

DISABILITY OUTCOMES AND DOSE ESCALATION IN RHEUMATOID ARTHRITIS PATIENTS TREATED WITH TUMOR NECROSIS FACTOR BLOCKERS: A COMPARATIVE EFFECTIVENESS ANALYSIS

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OBJECTIVES: Previous cohort studies using US commercial insurance claims of rheumatoid arthritis (RA) patients have observed higher dose escalation rates for patients treated with tumor necrosis factor-α (TNF) blockers infliximab (INF) or adalimumab (ADA) than for etanercept (ETN). However, such databases cannot be used to determine whether dose escalation is associated with improved clinical outcomes. We compared functional disability and dosing history between patients treated with TNF blockers using data from a large, prospective observational registry (Arthritis, Rheumatism, and Aging Medical Information System; ARAMIS) of RA patients in the US. **METHODS:** ARAMIS enrolled adult physician-diagnosed RA patients. Patients who met following inclusion criteria were selected: treated with a TNF blocker for ≥9 months; had no biologics 6 months before index TNF treatment; and reported a Health Assessment Questionnaire Disability Index (HAQ-DI) at index and 9–15 months after index. Self-reported dosing information was validated by telephone follow-up, medical, billing, or retail pharmacy prescription records. Dose escalation was defined as dosing above first ADA/ETN or third INF dose. Multivariate models compared HAQ-DI change and dose escalation rates, controlling for variables that differed among INF, ADA and ETN patients at index. **RESULTS:** Approximately 351 patients (93 INF, 40 ADA, 218 ETN) met study criteria. Subjects were mostly female (83%), Caucasian (88%), and had mean disease duration of 18.9 years. HAQ-DI change scores at 9–15 months did not differ by treatment (–0.10, –0.08, and –0.12 points for INF, ADA, and ETN, respectively; $P = 0.52$). Dose increases were observed in 1.4% of ETN patients, as compared with 10.8% of INF ($P < 0.001$) and 12.5% of ADA patients ($P = 0.004$, both vs. ETN). HAQ-DI change was associated with pre-index HAQ-DI score and disease duration (both $P < 0.05$). **CONCLUSIONS:** This study showed dose escalation in fewer ETN than INF or ADA patients, but similar improvements in functional disability.

PMS3

IMPROVEMENT IN EFFICACY AND SAFETY OUTCOMES AFTER CERVICAL ARTHROPLASTY VERSUS STANDARD ANTERIOR CERVICAL DISECTOMY AND FUSION (ACDF) SURGERIES: A META-ANALYSIS OF PUBLISHED RCTS

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BACKGROUND: Cervical arthroplasty has been used successfully worldwide for over a decade in patients with cervical degenerative disc disease (CDDD). Several RCTs have documented the clinical advantage of arthroplasty vs. fusion for this patient population. Synthesis of outcomes from published RCTs is needed to consolidate the evidence-base for arthroplasty in CDDD. **OBJECTIVES:** To examine current evidence of safety and efficacy in the use of arthroplasty to treat CDDD and conduct a pooled analysis of high level comparative outcomes for arthroplasty versus fusion. **METHODS:** A systematic search of the PubMed, EMBASE, MEDLINE, CRD York, and Cochrane Library databases, plus hand searching of grey literature was undertaken in January 2010. **RESULTS:** A total of 554 non-duplicate citations were retrieved. Only three studies of arthroplasty versus fusion with 2 years follow-up met all inclusion criteria and were of reasonable quality (according to GRADE criteria) to pool. a meta-analysis was conducted using RevMan5 software (Cochrane 2008). Persons undergoing single-level arthroplasty had significantly improved neurological success (RR 1.14, 95% CI [1.07, 1.21] $P < 0.0001$), Neck Disability Index (NDI) success (RR 1.13, 95% CI [1.05, 1.22] $P = 0.001$) and overall success (RR 1.22 95% CI [1.12, 1.33], $P < 0.00001$) at 2 years post surgery compared to fusion. Secondary surgeries (any revision, removal, or re-operation of the implant or supplemental fixation) after 2 years were also significantly lower with arthroplasty (13/621) compared to fusion (39/592), [0.32 95% CI [0.17, 0.59) $P = 0.0003$]. Total number of patients undergoing reoperations at adjacent levels was lower in arthroplasty-treated patients (9/621) vs. ACDF (17/592), however it was not statistically significant ($P = 0.09$). Given the small numbers of patients undergoing reoperations at adjacent levels, longer term results are needed to increase precision of this estimate. **CONCLUSIONS:** A formal pooled analysis of 2-year RCT data demonstrates clinically significant improvements in efficacy and safety outcomes in CDDD patients who have undergone arthroplasty versus standard fusion.

PMS4

NUMBER NEEDED TO TREAT FOR PATIENTS TO REPORT BROAD RELIEF FROM THE BURDEN OF RHEUMATOID ARTHRITIS WHEN TREATED WITH CERTOLIZUMAB PEGOL PLUS METHOTREXATE

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OBJECTIVES: To determine in patients with RA the number needed to treat (NNT) to achieve minimum clinically important differences (MCIDs) in multiple patient